

REMARKS

A. Summary of the Invention.

The invention provides the art with the discovery that fatty acid esters can be used as pediculocidal agents that will kill ectoparasites such as lice within an hour. As presently claimed, the invention identifies twelve fatty acid esters out of a genus of dozens that possess the requisite activity.

B. Response to Rejection under Section 102(a) & (e), based on Pearlman.

Claims 1-4, 7, 12-15, 18, 32 and 33 stand rejected under Section 102(a) and (e) based on Pearlman, US Patent No. 6,303,581, on the basis that the composition of Pearlman is assertedly the same as the claimed composition:

Fatty esters @ 10%, or from 0.1-80% are applied to coat hair & lice, in nontoxic solvents. Neither alcohol or insecticide is required.(col. 12, lines 39-42). Fatty esters are at col. 13, top.Solvents can be water, ether, ketones, for example(col. 13 lines 7-43).

Although the Action acknowledges that Pearlman neither teaches nor suggests that fatty acid esters might be pediculocidal within the 1 hour time frame recited, it appears to conclude that the property is inherent, if unrecognized, such that the reference anticipates the present claims (Action, at page 3). Applicant respectfully disagrees.

Not even Pearlman suggests that all fatty acid esters possess properties useful in treating lice. Instead, he suggests that any surfactant—a staggeringly vast array of compounds¹—might be effective against lice. No guidance is provided as to the structural or physical properties that must be present in such active compounds. Rather, the only characterization of which compounds embraced by the disclosure are useful is a functional one: “[d]riable pediculostatic agents useful in the methods and kits of the present invention are characterized by their ability to induce an immersion reflex in lice in their wet form and to keep the lice in the immersion reflex once dried.” (Col. 10, lines 1-4).

How to choose among the thousands of potentially active compounds identified by Pearlman? The reference offers only an invitation to test each compound, one at a time, and see what happens: “1. *Contact a louse with an agent suspected of being a pediculostatic agent; and 2. Observe whether the louse becomes immobile.*” (Col. 10, lines 10-13). It’s difficult to imagine a more sweeping invitation to extensive experimentation. Clearly, however, one can only expect that many of the tested compounds would necessarily fail, or the suggestion to test them *ad infinitum* would be meaningless. Therefore, it can’t be said that Pearlman inherently teaches that all fatty acid esters have even the pediculostatic (immobilizing) properties of his invention, much less the pediculocidal properties of the present invention.

To the contrary, for guidance as to which species among the broad genus of fatty acid esters might have the required characteristics, Pearlman states only that: “fatty acid esters of fatty alcohols and other alcohols such as polyalkylene glycols (including propylene glycol and polyethylene glycol) sorbitan, and sucrose [*sic*—neither sorbitan

¹ For example, US Patent No. 6,958,314 has described the number of nonionic surfactants alone as being “almost infinite.” (Col. 1, lines 25-30). As to fatty acid esters, the term encompasses dozens of compounds, from long chain to short chain esters, esters of higher or lower alcohols, saturated to unsaturated esters, and common fats and oils.

nor sucrose are fatty acid esters or alcohols]" might be of use (Col. 12, lines 11-21). No specific fatty acid ester other than the glycols are identified as being *actually* useful. Therefore, the ordinary artisan is merely left with Pearlman's invitation to experimentation: put the compound on a louse, see what happens. Given the sheer number of experiments one would have to perform to identify which of all the species of fatty acid esters as a genus might immobilize lice as required by Pearlman, there is little question that the effort required by such experimentation would be undue.

In contrast, it will be appreciated that the present claims identify for the artisan twelve particular fatty acid esters one can use to kill lice as claimed within 1 hour of application: myristate, laurate, palmitate, stearate, arachidate, behenate, lignocerate, palmitoleate, oleate, linoleate, linolenate, and arachidonate (Claims 1 and 12). The esters are identified in a Markush grouping with closed language: "the group...*consisting of*...", rather than open language, as asserted at page 2 of the Action. The characteristics of the recited esters vary—for example, some are saturated while others are not—and so they are not easily selected for inclusion in a group by their known properties. Rather, what is common amongst them is their claimed activity.

Without testing the claimed esters as directed by Pearlman (treat a louse, see what happens), it cannot be said if any of them immobilize lice as required by Pearlman. Moreover, nothing in Pearlman suggests in any way that the specific fatty acid esters of the invention would have the presently claimed property of killing lice within an hour. To the contrary, Pearlman suggests that such killing would not occur, if at all, for at least 8 hours after application:

CETAPHIL® Cleanser has the ability rapidly to trigger the "immersion reflex" in head lice. Both in vivo and in vitro, lice coated in CETAPHIL® Cleanser became immobilized within 6 seconds. On the patients' scalp, the lice became totally immobilized, floating on the scalp in the Cleanser. They were easily removed by forceps without any effort to escape or to grasp the hair shaft to stay in place. Under the microscope, they were immobile did not respond to being

touched, and lost their normally visible gut motility. They remained immobilized as long as they were in the Cleanser. ***This phenomenon was observed for periods ranging from 6 seconds to 4 hours. At any point prior to drying the cleanser, the louse could be removed from the Cleanser and usually awakened and resumed crawling. When immersed overnight in CETAPHIL® Cleanser (12 hours) the lice died.***

When CETAPHIL® Cleanser was dried onto lice (6 lice tested), the lice remained immobile. When the dried agent was removed by redissolving it in water after 4 hours of contact, the lice recovered and regained mobility. When left on the lice for more than 8 hours before redissolving, the lice died.

Pearlman, '581, at Col. 14, line 64 to Col. 15, line 18, emphasis added.

Therefore, if one were to follow Pearlman's instructions to apply his candidate pediculostatic compounds to lice, one might at most expect the lice to become immobilized. One would have no reason to evaluate morbidity, as Pearlman explicitly teaches away from any expectation that it would occur. Moreover, if one were to serendipitously choose to evaluate morbidity among treated lice, Pearlman's dearth of guidance as to which fatty acid esters to select even for their "pediculostatic" properties would require repeated experimentation using dozens of different fatty acid esters of varying characteristics before one might arrive at the specific fatty acids whose pediculocidal activity is now claimed.

"An invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004); cert. denied (2006) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been

made or whether the prior art reference merely invites further experimentation to find the species).

The Federal Circuit's observation in *Metabolite* is directly on point here: all the Pearlman reference does is point to a genus (surfactants, including fatty acid esters) and offer the art a guidance-free invitation to experiment within it (treat a louse, see if it becomes immobilized). Even if such a deficient disclosure was sufficient to support claims to Pearlman's own invention (immobilizing lice for their physical removal), it falls well short of rendering the presently claimed invention anticipated by inherency.

Nor is the possibility that extensive experimentation might lead one to stumble upon the invention sufficient. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted, emphasis added). Here, sheer guesswork (and a lot of it) would be required to apply Pearlman's suggestion of treating lice to see how they are affected to the dozens of species embraced by his disclosed genus of fatty acid esters, with no reasonable basis to believe—contrary to Pearlman's teaching—that any of the species would kill lice within an hour of application as claimed.

The same facts support the conclusion that Pearlman does not enable the presently claimed invention, and so cannot anticipate it. In that respect, to be anticipating, a prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003); *Helifix, Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000); *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986). Prior art is not enabling so as to be anticipating if it does not enable a person of ordinary skill in the

art to carry out the invention. See *Elan Pharms., Inc. v. Mayo Found.*, 346 F.3d 1051, 1057 (Fed. Cir. 2003) (remanding the case to the district court for a determination of whether the prior art reference enabled persons of ordinary skill to make the invention without undue experimentation).

For all of the above reasons, Applicants respectfully submit that the pending claims are not anticipated by Pearlman. Reconsideration and withdrawal of the rejection under Section 102(a) and/or (e) is therefore requested.


CONCLUSION

All of the pending claims (1-4, 7-16, 18-22, 24-26, and 32) are believed to be in condition for allowance. Reconsideration of the claims rejections and objections is therefore requested as outlined above.

The Commissioner is hereby authorized to charge \$525.00 as payment for the Petition for Three-Month Extension of Time fee, small entity, to Deposit Account No. 07-1896. No other fee is deemed necessary in connection with the filing of this paper. However, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896.

Respectfully submitted,

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